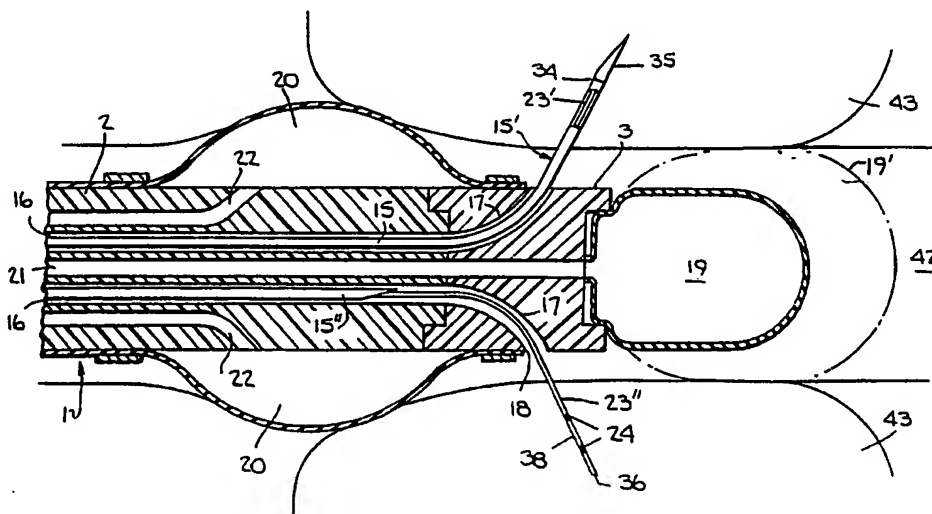




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>5</sup> :</b>  <b>A61B 17/36</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 92/10142</b>  <b>(43) International Publication Date:</b> 25 June 1992 (25.06.92)
<b>(21) International Application Number:</b> PCT/US91/08388  <b>(22) International Filing Date:</b> 18 November 1991 (18.11.91)  <b>(30) Priority data:</b> 625,332                      10 December 1990 (10.12.90)    US  <b>(71) Applicant:</b> PFIZER HOSPITAL PRODUCTS GROUP, INC. [US/US]; 235 East 42nd Street, New York, NY 10017 (US).  <b>(72) Inventor:</b> MAKOWER, Joshua ; 1 Wyndham Court, Nanuet, NY 10954 (US).  <b>(74) Agents:</b> RICHARDSON, Peter, C. et al.; Pfizer Inc., 235 East 42nd Street, New York, NY 10017 (US).		<b>(81) Designated States:</b> AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (Utility model), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** A DEVICE AND METHOD FOR INTERSTITIAL LASER ENERGY DELIVERY



**(57) Abstract**

Disclosed is a catheter and moveable needle system (15', 15'') which places one or more fiber optic elements (23', 23'') and thermo-measuring devices (24) through a body passageway wall and into the bulk of an adjacent organ (43). The catheter is positioned adjacent to the organ and the needles are extended to mechanically puncture the wall and move into the organ with the fiber optic elements. The needle may be withdrawn into the catheter before delivery of laser energy or remain in the organ to serve as an aspiration-irrigation vehicle. Lumens (16) provided in the catheter for carrying the hollow needles may likewise be used for aspiration or irrigation of the passageway. A dilation balloon (19, 20) may be provided in order to temporarily fix and support the catheter while the needle is inserted into the organ. The temperature of the area being treated is monitored by thermomeasuring devices provided on the fiber optic elements. Small puncture holes created by the hollow needles heal quickly and minimize risk of infection.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU <sup>+</sup>	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE*	Germany	MC	Monaco	US	United States of America
DK	Denmark				

+ Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

-1-

5

A DEVICE AND METHOD FOR INTERSTITIALLASER ENERGY DELIVERYField of the Invention

This invention relates to an apparatus and method for laser energy delivery to internal organs for treatment thereof and in particular, treatment of diseases of the prostate, including benign prostatic hypertrophy (BPH) and prostatic cancer. More particularly, the invention relates to a catheter including a needle means for delivering a laser guiding optical fiber directly to the area to be treated by energy delivery.

Background of the Invention

Prostatic disease is one of the most common diseases in men in the United States. Prostatic disease, as referred to here, includes benign prostatic hypertrophy (BPH) and prostatic cancer. These two etiologies affect a majority of men over the age of 60.

The clinical symptoms of BPH include urinary tract outlet obstruction due to an enlarged prostate. The etiology of BPH, while not fully understood, has focused on two hypotheses. The first hypothesis has identified the hyperplastic cell morphology as a stromal cell disease. The second hypothesis has investigated the effects of prohormone dihydrotestosterone (DHT), which is the primary mediator of androgen action in the prostatic cells.

The currently accepted treatment for BPH is transurethral resection of the prostate (TURP). Approximately 300,000 TURPs per year are performed to treat this disorder in the United States. Morbidity and mortality for TURP are 17 and 1 percent, respectively, for all age groups combined. Higher complication rates occurs in older populations with an annual surgical and hospitalization cost in excess of \$1 billion per year.

Among other treatment available for the condition of BPH are pharmacological means such as vasoactive and antiandrogen agents. The vasoactive drugs primarily used are  $\alpha_1$  receptors, without effecting the  $\alpha_2$  receptors. These drugs reduce smooth muscle tone within the prostate, which is in part responsible for the mechanical obstruction of urine through the prostatic urethra. Data on this treatment suggest good efficacy in relieving symptoms, but it should be noted that mechanical obstruction may still exist and may promote the development of urinary tract infection bladder stones and possible upper urinary tract obstruction.

-2-

Antiandrogen agents have also been used to reduce the symptoms associated with BPH. The primary function of these antiandrogen blockers is to reduce the effects of DHT activity in the prostate by competing for the androgen receptors. While there has been evidence of the clinical efficacy of these agents in reducing the size of the prostate and relieving the symptoms associated, the problem with this pharmacological intervention has been the slow onset of therapeutic action.

With regard to prostatic cancer, both the incidence and mortality are on the rise. It is expected that over 100,000 new cases will be diagnosed this year alone, with some 30,000 cases proving fatal.

While the etiology of prostatic cancer is also not well known, it has been suggested that this disease is either biochemically or genetically induced. The symptoms of prostatic cancer are insidious and are usually not clinically manifest until the course of the disease is far advanced. The current treatment of choice for prostatic cancer is to perform a radical prostatectomy which involves surgical excision of the prostate gland.

In both cancerous and benign conditions, the cause of the reduction of the available flow channel in the lumen of the vessel i.e., the prostatic urethra, is an externally induced compression of the vessel wall due to the proliferation of epithelial, prostatic cell tissue. In order to be effective, treatment of diseases of the prostate must cause a reduction in the mass of the prostatic tissue responsible for creating the compressive forces on the urethra which results in the obstruction of flow through the lumen of the urethra. This is accomplished either by surgical excision of the tissue or by other means which will cause necrosis of the cells and shrinkage of the tissue mass.

Laser energy may be applied at at least four different levels in order to affect the tissue being treated. The first and lowest level of laser energy delivery is induced fluorescence. At this level, laser light energy is directed into the cells to reversibly energize the cells. The fluorescence effect occurs as energy is given off in returning to the lower energy state. The next level results in cellular change due to photo-effect. Laser light energy is directed into the cells at an irreversible level, but below that required to produce hyperthermia. At this level of energy delivery, cellular change (including necrosis if desired) occurs at the molecular level due to the photo effects of laser light. The third level of energy delivery results in hyperthermia by raising cells to a temperature level (42-44°C) where necrosis occurs. The fourth level of energy

delivery is vaporization. This requires delivery of laser energy sufficient to produce temperatures of about 100°C in the tissue being treated.

Laser hyperthermia has been suggested as a possible means for necrosis of diseased prostatic cells. But, to date, practical means for applying laser hyperthermia  
5 have not been developed.

U.S. patent No. 4,672,963 to Barken discloses an apparatus and method for laser surgery which uses a computer controlled, ultrasonic imaging system to position a laser light guide within a patient. This patent discusses prostatic disease and purports to provide suitable apparatus for treatment; however, no specific means for  
10 directing the laser energy to the area in need of treatment is disclosed. Barken states only that an optical light guide can be inserted into the body through a relatively small surgical opening.

U.S. Patent No. 4,950,267 to Ishihara et al. discloses a laser beam treatment device for an endoscope. The endoscope delivers a laser probe to a position in a  
15 body, from which the laser probe is thrust into the part of the organ to be treated. The disclosure is not specific as to how the laser probe is inserted into the organ. Known fiber optic elements generally do not possess sufficient rigidity to mechanically puncture a body structure such as the urethral wall. Furthermore, Ishihara discloses a number of alternative laser probes having blunt or rounded distal ends. It is unlikely that these  
20 probes could be mechanically forced into an organ even if they possessed substantial structural rigidity. Thus, it appears that insertion of at least some of the Ishihara laser probes requires coincidental application of laser energy to burn a hole into the organ. This method of insertion is undesirable because, upon withdrawal of the instrument, a small hole will remain with the possibility of abscess and infection.

25 The above-mentioned patents discuss only laser hyperthermia. They do not address possible treatments using the other three energy levels previously discussed. Thus, there is a need in the field of medical laser energy delivery, including treatment of prostatic disease, for an effective means for delivering various laser energy levels to the areas to be treated. In the treatment of prostatic disease, alternatives are needed  
30 to the more radical and consequently complicated and more dangerous surgical procedures which currently are the treatments of choice, namely, TURP for BPH and radical prostatectomy for prostatic cancer.

### Summary of the Invention

It is therefore an object of the present invention to provide a practical means for laser energy delivery to the prostate or other organs adjacent to a body passageway.

It is also an object of the present invention to provide a procedure for treatment  
5 of the prostate or other organs which is potentially bloodless compared to known procedures and is a less invasive single procedure that can be performed on an outpatient basis. According to the present invention, these and other objects are achieved by providing a catheter with at least one moveable hollow needle that carries a fiber optic element. In this manner, the catheter may be inserted into a body  
10 passageway adjacent to the organ to be treated. The moveable needles are extendable to mechanically puncture the passageway wall and carry the fiber optic elements into the organ to the area to be treated. After the desired level of laser energy has been applied to the area being treated, the fiber optic elements and hollow needles are withdrawn into the catheter. The catheter is then removed from the passageway.  
15 Thus, laser energy delivery with the present invention leaves behind only small puncture wounds in the passageway wall. Due to the nature of the mechanical puncture wounds they are capable of healing quickly with a minimum risk of infection.

The present invention generally includes the following components: At least one fiber optic element for delivering laser light from a laser energy source to the area of  
20 the prostate to be treated. The fiber optic element is slidably received in and carried by a hollow needle. The hollow needle has a sharpened distal end in order to easily mechanically puncture the passageway wall and enter the organ to carry the fiber optic element to the area to be treated. The fiber optic element is slidably disposed within the needle to allow relative axial movement between the element and the needle. Thus,  
25 the needle is retractable separately from the fiber optic element.

The needle is received in a flexible catheter shaft which is inserted into the passageway. Any number of needles may be carried in the catheter shaft. The number of needles is limited only by the diameter of the catheter shaft. Generally, one fiber optic element is carried by each needle. The needles are slidably received in needle  
30 lumens within the catheter shaft. At the distal end of the catheter shaft a distal tip is provided to guide the needles outward and into the prostate. The means for directing the needles may be simply a number of curved channels communicating with the

-5-

needle lumens to guide the needles in the desired direction, or may comprise a bearing and track system for guiding each needle.

The present invention also include a means for actuating and controlling the needles in order to move each needle between a first position, sheathed within the catheter shaft and distal tip, and a second position, extending out of the distal tip and into the organ. The actuation and control means is capable of moving each needle between the first and second positions, both independent of the fiber optic element and in conjunction with the fiber optic element. By using a suction-irrigation device with the hollow needle, the hollow needle may serve as a vehicle to aspirate or irrigate the area receiving laser treatment, or the needle may completely withdrawn into the catheter shaft. A suction and irrigation device may also be used in communication with the needle receiving lumen in the catheter shaft to provide suction or irrigation in the passageway at the point where the fiber optic element enters the wall.

To support the needle during puncturing and insertion into the passageway wall means for temporarily fixing the catheter in the passageway is provided. This means comprises at least one inflatable dilation balloon surrounding at least part of the distal end of the catheter shaft and distal tip. A lumen is provided in the catheter shaft to direct an inflation fluid to the dilation balloon.

In one alternative embodiment the needle is provided with a steering fiber in order to guide the needle once it has entered the prostate. Tension induced in the steering fiber causes the needle to bend and thus change direction.

#### Brief Description of the Drawing

The features and advantages of the invention will be more readily apparent from the following detailed description of the preferred embodiments, illustrated in the drawing figures, wherein:

FIG. 1 is a schematic view of the apparatus of the present invention showing the catheter and ancillary devices;

FIG. 2 is a section view of the catheter tip of a preferred embodiment of the apparatus of the present invention;

FIG. 3 is a detailed view of a portion of FIG. 2 showing the needle and needle lumen;

FIG. 4 is a section view of the catheter tip of an alternative preferred embodiment of the apparatus of the present invention;

FIG. 5 is a section view of an alternative embodiment of the distal tip and needle director channels according to the present invention;

FIGS. 6a and 6b are cross sectional views of the tip shown in FIG. 5, taken along lines 6a-6a and 6b-6b, respectively;

5        FIG. 7 is a section view of a preferred embodiment of a needle used in the apparatus of the present invention;

FIG. 8 is a section view of a steerable needle used in the apparatus of the present invention;

FIG. 9 is a cross sectional view of the needle of FIG. 8, taken along line 9-9;

10       FIG. 10 is a section view of the catheter tip according to an alternative preferred embodiment of the apparatus of the present invention; and

FIG. 11 is a section view of the catheter tip of a preferred embodiment of the apparatus of the present invention shown in transurethral insertion made with the needles and fiber optic element in various stages of deployment in prostatic tissue.

15        Detailed Description of the Preferred Embodiments

Shown generally in FIG. 1, the present invention includes catheter 1, which delivers a needle system (shown in detail in FIGS. 3 and 7-9) that places one or more fiber optic elements and thermo-measuring devices through the urethral or rectal wall and into the bulk of the prostate mass. Laser energy is then delivered by the fiber optic element to hyperthermally treat selected areas. For the purposes of clarity and conciseness, the detailed description is made with reference only to the urethra, rectum and prostate. This is not intended to be limiting of the present invention, as it will be readily appreciated that the present invention is useful for laser energy delivery to any organ or body part adjacent to a passageway accessible by a catheter.

25        Catheter 1 has a semi-rigid or flexible shaft 2 ending at distal tip 3 and beginning at proximal end 5. The diameter of catheter 1 may be small enough to allow it to be inserted down the shaft of a known urethroscope, proctoscope or resectoscope. Alternatively, catheter 1 may be much larger without departing from the scope of the invention; and, thus be inserted directly into the rectum or urethra.

30        Needle control cable 9 extends from proximal end 5 and connects the needle system to an external needle actuation and control means 8. In practice, the configuration of needle control cable 9 will vary depending on the particular

-7-

embodiment of the invention used. These variations will be apparent to persons skilled in the art based on the description of the alternative embodiments below.

In addition to needle actuation and control means 8, one or more of the following devices are used to assist in positioning and operating the invention: laser  
5 energy source 11, suction-irrigation device 12, thermo-monitoring device 13, and fiberoptic visualization apparatus 14. These devices cooperate with catheter 1 through multi-device interface 10. The operation and function of each of these known devices should be understood by those skilled in the art. The cooperation of each device with the present invention will be better understood after the various components of the  
10 present invention have been described in greater detail below.

FIG. 2 illustrates one preferred embodiment of the needle system and distal tip 3 of the present invention. Distal tip 3 is secured to the distal end 4 of catheter shaft 2. Needle 15 lies in needle lumen 16 within shaft 2. A long, spinal-type needle with sufficient flexibility to follow the urethral or rectal passageway is shown. Any similar  
15 long, fine needle may be used. Needle director channel 17 is provided in distal tip 3, in communication with needle lumen 16. Director channel 17 opens on the periphery of distal tip 3, through needle outlet 18.

When catheter 1 has been placed within the urethra or rectum, with distal tip 3 adjacent to the prostate, needle 15 may be advanced by actuation and control means  
20 8. In practice, various actuation means are possible. A person of ordinary skill in the art will recognize hydraulic, spring loaded, mechanical translational or rotational cable, shape memory alloy, or electro-magnetic mechanisms as useful for this purpose. When advanced, needle 15 extends from lumen 16 into director channel 17 and is thus curved outward, toward the urethral or rectal wall and into the prostate.

25 The position of catheter 1 and extension of needle 15 may be observed using various visualization means such as fluoroscopy, magnetic resonance spectroscopy, proctoscopy, urethroscopy, transrectal ultrasound, and transurethral ultrasound. Specific targeting of certain types of small lesions in the prostate (i.e., prostate cancer) will require the use of interstitial guidance such as ultrasound, MRI or fluoroscopy.  
30 More massive benign conditions, such as BPH, may not require such guidance.

To maintain the position of the catheter and dilate the urethra or rectum (compress the prostate) while needle 15 is entering the prostate, one or more balloons may be used. In the embodiment shown in FIG. 2, shaft balloon 20 and tip balloon 19

are used for these purposes. An inflation substance such as saline or air is delivered through lumens 22 and 21, respectively. By pressing against the passageway wall, the balloons fix the catheter to provide a firm base for supporting the needle as it punctures and enters the prostate.

5        Additionally, the effectiveness of the laser energy delivery can be increased by restricting blood flow to the tissue cells to be necrosed. For example, effective laser hyperthermia requires that the temperature of the target cells be raised to a minimum of about 42.5°C and maintained at that temperature for a specified period of time. Blood supply to the diseased target cells acts as a heat sink that absorbs thermal  
10    energy and prevents those cells from being heated sufficiently. The heat sink effect prevents the target cells from reaching the desired temperature without raising the temperature of surrounding normal tissue cells high enough to cause damage. The dilation balloon(s) press against the prostate to restrict blood flow to the target cells and reduce the unwanted heat sink effect.

15        The details of needle 15 are best seen in FIG. 3. Fiber optic element 23 is slideably received in lumen 32 in the needle. In a preferred embodiment, fiber optic element 23 is simply a bare optical fiber. Modifications such as cladding and shaped ends may be used (see FIG. 8). One or more thermo-measuring devices are attached to element 23 to monitor the temperature  
20    at the energy delivery location. For this purpose two thermocouples 24 are shown in FIG. 3. Fiber optic thermo-measuring devices also may be used. The leads for thermocouples 24 are attached to fiber optic element 23 and lie within lumen 32. Lumen 32 also may be used for aspiration or irrigation.

FIG. 7 illustrates a possible alternative embodiment for needle 15. Instead of  
25    being formed as a single piece, the needle shown in FIG. 7 has a sharpened needle tip 34 joined to a flexible needle shaft 33 by joint 35. Tip 34 is made of medical grade stainless steel and sharpened to a razor-like edge. Shaft 33, as are all other components, is made of standard bio-compatible plastic which may be selected by those of ordinary skill in the art. Again, central lumen 32 is provided within the needle  
30    to carry the fiber optic element and allow for aspiration or irrigation.

FIG. 4 illustrates an alternative embodiment of the present invention wherein the dilation and fixation means is formed as a single balloon 19a surrounding distal tip 3 and proximal end 4 of catheter shaft 2. Needle outlets 18 are provided in balloon 19a

-9-

to allow the needles to pass from director channels 17 into the prostate. Balloon 19a is inflated by one or more fluid lumens 21. This configuration concentrates the blood restricting and supporting effects of balloon 19a around the point of entry of the needles into the prostate.

5           Distal tip 3, shown in FIG. 1, is provided with a single needle director channel 17 for a single needle. It will be readily appreciated that multiple needles may be utilized, with the number being restricted only by the diameter of catheter 1. FIGS. 5 and 6 illustrate an alternative embodiment of a distal tip 3a having five director channels 17 to accommodate five separate needles. The five separate director channels 17  
10 alternatively may communicate with a single large lumen in catheter shaft 2 or director channels 17 may individually communicate with five separate needle lumens provided in catheter shaft 2.

Referring to FIGS. 8 and 9, a steerable needle according to the present invention may be described. In this embodiment, a needle steering fiber 39 is provided within  
15 lumen 32. Steering fiber 39 exits the needle through opening 40 near the needle tip. Steering fiber 39 is fixed to the needle adjacent the sharpened tip at joint 41. Tension induced in steering fiber 39 causes the needle to bend due to the eccentric positioning of the steering fiber within lumen 32. This bending allows the surgeon to steer the needle to the precise spot where hyperthermia is required, after the needle has  
20 punctured and entered the prostate.

FIG. 8 also illustrates a possible embodiment of fiber optic element 23. As shown in FIG. 8, optical fiber 36 is provided with cladding 38 and spherical end 37 in order to dissipate the laser energy over a wider angle at the point of delivery. Cladding 38 is standard, commercially available optical cladding.

25           FIG. 10 shows a further alternative embodiment of the catheter distal tip 3 according to the invention. In this embodiment, needle 15 is advanced forward by manipulation of cable 25, attached at the proximal end of needle 15. The correct movement of needle 15 is ensured by bearing 26, which moves with needle 15 and rides smoothly in track 27. Needle port 18a may have a breakthrough covering or may  
30 be exposed as shown.

In order to finally position needle 15, catch 28 is retracted by cable 31 and bearing 26 is pushed past the catch. Cable 31 is then released and compression spring 29 causes catch 28 to hold needle 15 in place due to its biasing action around

-10-

pivot 30. Thus, catch 28 adds both directional assistance and provides resistance to maintain needle 15 in position. The needle may be definitively locked in position by locking cable 31. Spring 29 may be a plastic or metal spring.

Attached at the base of needle 15 is an aspiration/irrigation lumen 32 which  
5 allows the needle to introduce the fiber optic element 23 (with thermocouples 24) and act as an irrigation or suction vehicle.

The overall operation of the present invention may be explained by reference to FIG. 11. Catheter 1 is inserted into the urethra 42 (or rectum) and placed adjacent to the area of the prostate 43 where delivery of laser energy is desired. Shaft balloon 20  
10 and tip balloon 19 (inflated at 19') are inflated as required to secure the position of catheter 1 and compress the prostate. As shown in FIG. 11, catheter 1 employs distal tip 3a (FIG. 5) and needles 15 are formed in two parts as shown in FIG. 7.

FIG. 11 shows the present invention at two different stages of operation. In the top half of FIG. 11, needle 15' has just been extended to puncture the urethral wall and  
15 enter the prostate 43. As needle 15' is moved into the prostate, it carries with it fiber optic element 23', with thermocouples 24 attached. Once the needle 15' has moved to the desired location in the prostate, the needle may be either withdrawn, leaving the fiber optic element 23' in place, or remain in position to act as a irrigation or suction vehicle. If vaporization is to be employed, aspiration through the needle is necessary  
20 to remove gasses produced. Control and actuation means 8 is used to control the position of the fiber optic elements with respect to the needles and to control the position of both with respect to the catheter. If necessary, irrigation or aspiration may be conducted through needle lumen 16, director channel 17 and needle outlet 18 which opens into the urethra 42 (or rectum). Aspiration or irrigation for both the needle and  
25 the catheter is provided by suction-irrigation device 12.

As shown in the bottom half of FIG. 11, needle 15" has been withdrawn into needle lumen 16, leaving fiber optic element 23" in place in the prostate 43. In this embodiment, fiber optic element 23" comprises optical fiber 36 surrounded by cladding  
30 38. Optical fiber 36 has a plain end, and thermocouples 24 are mounted in cladding 38. Laser energy is provided to the fiber optic elements from laser energy source 11 by known means. Thermocouples 24 are connected to thermo-monitoring device 13, which monitor the temperature of the area being treated in order to precisely control the energy delivery.

-11-

After the delivery of laser energy is complete, the fiber optic elements may be repositioned by further extension of the associated needles or by withdrawing the elements and repositioning catheter 1. Alternatively, if a steerable needle is used (such as shown in FIG. 8), the needle may be significantly repositioned without moving  
5 catheter 1. After energy delivery is complete, all needles and fiber optic elements are withdrawn and catheter 1 is completely withdrawn from the body.

The structure of the present invention also promotes recovery for the patient after the procedure is complete. Due to deep ablation of the tissue and the mode of delivery, only small needle-size puncture holes remain in the urethra. These will heal  
10 quickly, leaving the remaining deep necrotic tissue to sluff and be absorbed subepithelially. Any liquefied or vaporized materials may be suctioned while the needles are still in place. No drainage catheter is needed postoperatively and the procedure may be done on a one day surgery basis.

CLAIMS

1. Apparatus for laser energy delivery to an organ adjacent to a body passageway, characterized by:

5 a fiber optic element having a distal end for delivering laser light to an area of the organ to be treated;

hollow needle means for puncturing the passageway wall and organ and for carrying the fiber optic element through the puncture to the area of the organ to be treated, said fiber optic element slidably disposed within said needle means allowing relative axial movement between said element and needle means, said needle means  
10 being retractable separate from said element to expose the distal end of the fiber optic element to the area to be treated; and

catheter means for delivering said optical fiber optic element inside said needle means, to a position in the passageway adjacent to the organ to be treated.

2. Apparatus according to claim 1, wherein said catheter means is  
15 characterized by:

a tubular body having a distal end and a proximal end and defining a needle lumen for slideably receiving said needle means and

means for directing said needle means into the organ, including a channel communicating with the needle lumen and opening to the body passageway;  
20 and

suction-irrigation means communicating with said needle lumen for alternately aspirating and irrigating the passageway around the puncture as desired.

3. Apparatus according to claim 1, wherein

said needle means includes at least one tubular shaft needle having a  
25 sharpened distal end for puncturing the passageway wall and organ;

said tubular shaft needle defines a lumen for slideably receiving the fiber optic element; and

said lumen communicates with suction-irrigation means for alternately aspirating and irrigating the area of energy delivery as desired.

30 4. Apparatus according to claim 3, wherein said tubular shaft needle is characterized by a metal, sharpened needle tip joined to a flexible shaft.

5. Apparatus according to claim 3, wherein said needle is individually steerable.

-13-

6. Apparatus according to claim 5, wherein said needle includes:  
a peripheral opening defined by the tubular shaft spaced proximally from  
the distal end of the needle; and  
a steering fiber received in said needle lumen, and exiting said needle  
5 lumen through said peripheral opening, with said fiber being joined to the needle  
adjacent to the sharpened distal end, whereby the needle may be bent and steered by  
inducing tension in said steering fiber.
7. Apparatus according to claim 1, wherein:  
said needle means includes a plurality of individual tubular shaft needles,  
10 each needle having a sharpened distal end for puncturing the passageway wall and  
organ, and each needle defines a lumen for slideably receiving a fiber optic element;  
and  
said catheter means is characterized by:  
a tubular body having a proximal end and a distal end and defining a  
15 plurality of needle lumens equal in number to the number of said plurality of  
needles, with one needle slideably received in each needle lumen,  
a cylindrical distal tip attached the distal end of the tubular body, said  
distal tip having a plurality of curved channels equal in number to the number  
of needle lumens, each curved channel communicating with one needle lumen  
20 at the distal end of the tubular body and opening at needle outlets along the  
periphery of the distal tip to provide means for directing said needles into the  
organ, and  
means for temporarily fixing the tubular body and distal tip in the  
passageway relative to the passageway wall.
- 25 8. Apparatus according to claim 7, wherein said fixation means is  
characterized by:  
a first inflatable dilation balloon circumferentially surrounding the tubular  
body, disposed proximally relative to the needle outlets in the distal tip;  
an inflation lumen provided in said tubular body communicating with said  
30 first balloon;  
a second inflatable dilation balloon disposed at the distal end of the  
distal tip; and

-14-

an inflation lumen provided in said tubular body and extending through said distal tip in communication with the second balloon.

9. Apparatus according to claim 7, wherein said fixation means is characterized by:

5 an inflatable dilation balloon surrounding the distal tip and a distal portion of the tubular body, said balloon having a number of needle passageways equal to the number of needles, each needle passageway being aligned with and communicating with one of the needle outlets; and

an inflation lumen defined by the tubular body and communicating with  
10 the balloon.

10. Apparatus according to claim 1, wherein said fiber optic element is characterized by an optical fiber surrounded by optical cladding with a thermo-measuring device provided coaxially with said optical fiber.

11. Apparatus according to claim 10, wherein said optical fiber has a  
15 spherical distal end.

12. Apparatus according to claim 1, wherein said fiber optic element consists of a bare optical fiber with at least one thermo-measuring device provided thereon.

13. Apparatus according to claim 12, wherein said optical fiber has a  
spherical distal end.

20 14. Apparatus according to claim 1, further comprising means for actuating and controlling said needle means to move said needle means between a first position, sheathed within said catheter means, and a second position, extending out of said catheter means and into the organ to be treated, said actuation and control means being capable of moving said needle means between said first and second positions  
25 both independent of said fiber optic element and in conjunction with said fiber optic element, whereby said fiber optic element may be selectively positioned and repositioned in said organ by mechanically puncturing said organ as required.

15. The apparatus of claim 14 wherein the needles are actuated by means selected from the group consisting of hydraulic, spring loaded, mechanical translational  
30 cable, mechanical rotational cable, electromagnetic, and shape memory alloy.

16. Apparatus according to claim 1, wherein:  
said hollow needle means is characterized by:

-15-

a rigid distal needle portion having a proximal end and a sharpened distal end, said rigid portion defining a hollow passage for said fiber optic element,

a bearing mounted on said rigid needle portion,

5 a flexible control and actuation cable attached to the proximal end of the rigid portion, and

structure defining a lumen attached to the proximal end of the rigid portion, said lumen communicating with the hollow passage, slidably carrying said fiber optic element and providing means for aspirating and irrigating the area of energy delivery; and

10 said catheter means is characterized by:

a tubular body defining a needle lumen slideably receiving said actuation cable and lumen structure,

15 a cylindrical distal tip joined to the tubular body, said tip defining an internal channel communicating with said needle lumen and opening via a needle outlet on the periphery of the distal tip,

track means for receiving and guiding said bearing in said distal tip, said track means configured to guide the sharpened distal end of said rigid needle portion out of said needle outlet when said control and actuation cable is moved distally, and

20 means for selectively locking said rigid needle portion in a position extending out of said needle outlet.

17. Apparatus according to claim 16, wherein the rigid needle portion is stainless steel and the sharpened distal end has a razor-sharp edge.

25 18. Apparatus for laser energy delivery to an organ adjacent to a body passageway, characterized by:

at least one fiber optic element having a distal end for delivering laser light from a laser energy source to an area of the organ to be treated;

30 at least one tubular shaft needle having a sharpened distal end for mechanically puncturing the passageway wall and organ and for carrying said at least one fiber optic element through the puncture to the area to be treated, wherein said needle defines a lumen slideably receiving said at least one fiber

-16-

optic element for relative axial movement between said element and said needle;

5 catheter means for delivering said at least one needle and fiber optic element to a position in the passageway adjacent to the organ to be treated, said catheter means being characterized by a tubularly body having a distal end and defining at least one needle lumen receiving said at least one needle, said catheter means further comprising means for directing said at least one needle into the organ including at least one channel communicating with said at least one needle lumen and opening on the periphery of the tubular body;

10 means for individually actuating and controlling said at least one needle to move said needle between a first position, sheathed within said at least one needle lumen, and a second position extending out of said catheter means tubular body and into the organ to be treated, said actuation and control means being capable of moving said at least one needle between said first and second positions, both independent of said at least one fiber optic element received in said needle, and in conjunction with said fiber optic element, whereby said at least one fiber optic element and said at least one needle may be selectively positioned in said organ; and

15 means for temporarily fixing said tubular body and distal tip in said passage way to provide support for said at least one needle when puncturing the passageway wall and organ.

20 19. Apparatus according to claim 18, wherein said lumen defined by said at least one needle communicates with suction-irrigation means for alternately aspirating and irrigating the laser treated area as desired.

25 20. Apparatus according to claim 18, wherein said at least one needle lumen in the catheter tubular body communicates with suction-irrigation means for alternately aspirating and irrigating the passageway wall adjacent to the puncture.

21. Apparatus according to claim 18, wherein said fixation means is characterized by:

30 a first inflatable dilation balloon circumferentially surrounding the tubular body, disposed proximally relative to said at least one channel opening in the tubular body;

-17-

an inflation lumen provided in said tubular body communicating with said first balloon;

a second inflatable dilation balloon disposed at the distal end of the tubular body; and

5 an inflation lumen provided in said tubular body in communication with the second balloon.

22. Apparatus according to claim 18, wherein said fixation means is characterized by:

10 a dilation balloon surrounding the distal end of the tubular body, said balloon having at least one needle passageway aligned with and communicating with said at least one channel opening of the directing means; and

an inflation lumen defined by the tubular body and communicating with the balloon.

23. Apparatus according to claim 18, comprising five fiber optic elements,  
15 five tubular shaft needles, five needle lumens and five director means channels.

24. Apparatus according to claim 18, comprising five fiber optic elements and five tubular needles received in a single needle lumen communicating with five director means channels for individually receiving each of said needles.

25. A catheter device for laser energy delivery to the prostate by insertion  
20 into the urethra or rectum, characterized by:

at least one fiber optic element for delivering laser light from a laser energy source to the area of the prostate to be treated;

25 at least one hollow needle defining a lumen receiving said at least one fiber optic element, the number of needles equalling the number of fiber optic elements, said at least one needle having a sharpened distal end for mechanically puncturing the urethra or rectum and entering the prostate to carry said at least one fiber optic element received in said needle to an area to be treated, said fiber optic element being slidably disposed within said needle allowing relative axial movement between said element and needle, said needle  
30 being retractable separately from said element;

a flexible catheter shaft for insertion into the urethra or rectum, said shaft having a distal end and a proximal end and defining at least one needle lumen for slideably receiving said at least one needle;

-18-

a cylindrical distal tip attached to the distal end of the catheter shaft, said tip having means for directing said at least one needle out of the catheter in an oblique direction with respect to said distal tip, whereby said at least one needle may be guided into the prostate, said directing means including a channel in said tip communicating with said at least one needle lumen for passage of said

5

at least one needle, said channel opening along the periphery of the distal tip; means for actuating and controlling said at least one needle to move said at least one needle between a first position, sheathed within said catheter shaft and distal tip, and a second position, extending out of said distal tip and into the prostate, said actuation and control means being capable of moving said at least one needle between said first and second positions, both independent of said fiber optic element and in conjunction with said fiber optic element, whereby said fiber optic element may be selectively positioned and repositioned in the prostate by further mechanically puncturing the prostate as required;

15

means for temporarily fixing said catheter in the urethra or rectum to provide support for said needle when entering the prostate, said means comprising an inflatable dilation balloon surrounding at least a portion of the distal end of the catheter shaft, with a lumen defined by the catheter shaft for supplying an inflation fluid to the balloon; and

20

suction-irrigation means, communicating with the lumen defined by said at least one needle and with the needle lumen defined by the catheter shaft, for alternately aspirating and irrigating the area treated by the laser and an area adjacent to the puncture in the urethra or rectum.

25

26. A method for laser energy delivery to an organ adjacent to a body passageway, characterized by the steps of:

inserting into the passageway an apparatus including a catheter incorporating laser energy transmitting means, characterized by at least one fiber optic element carried within said catheter inside at least one moveable hollow needle, for transmitting laser energy to prostatic tissue;

30

positioning the catheter such that a tip thereof is approximately adjacent to the organ to be treated;

-19-

5        deploying said at least one moveable hollow needle housed in the catheter and carrying said laser energy transmitting means such that said at least one needle mechanically punctures the passageway wall and penetrates into the organ to bring said laser energy transmitting means into contact with the area to receive energy deliver;

         selectively positioning said at least one hollow needle between a fully extended position and a position fully withdrawn into said catheter, while leaving said transmitting means fiber optic element in the organ;

10        energizing the laser energy transmitting means;  
         directing laser energy onto the receiving area;

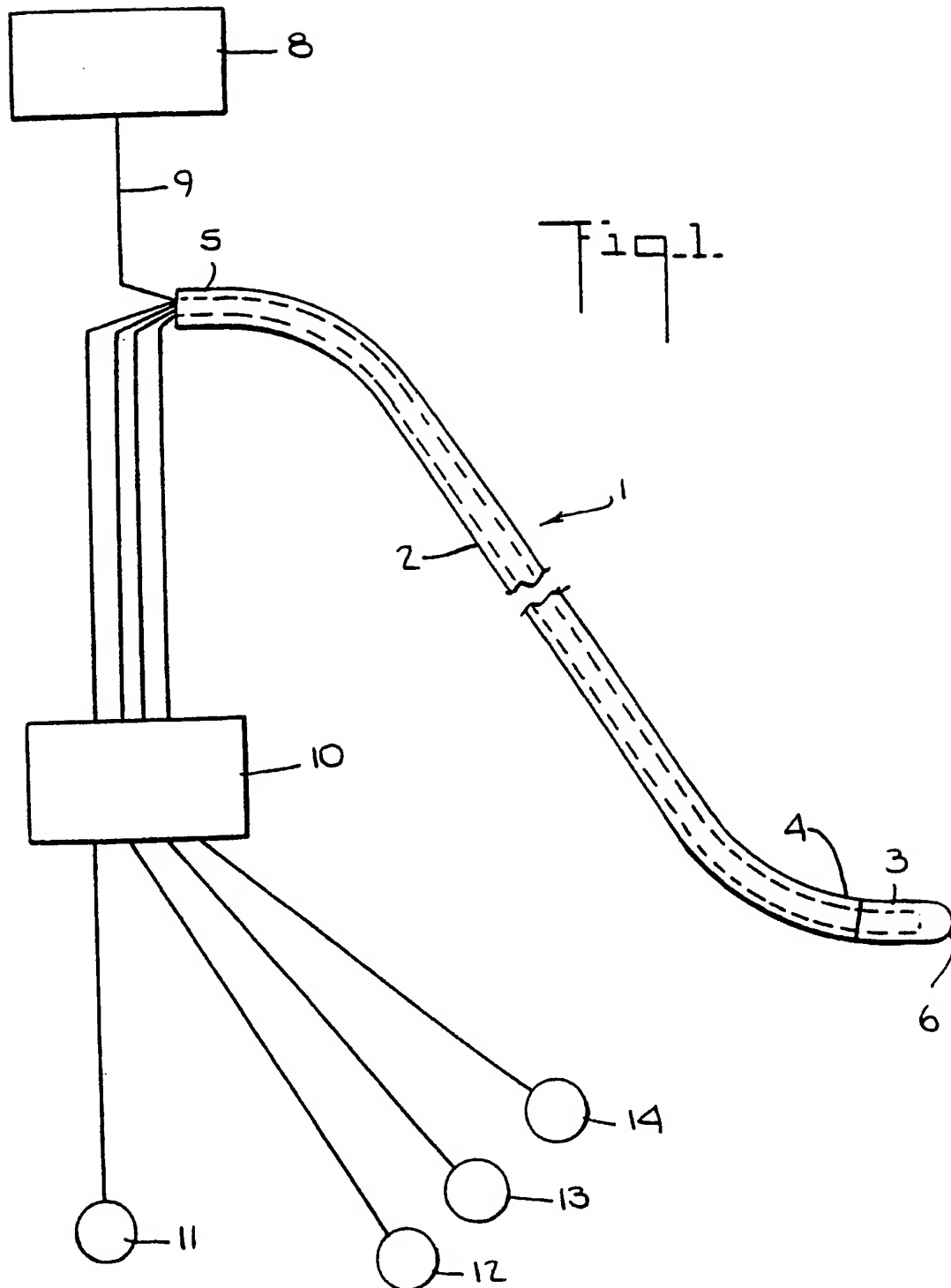
         aspirating and irrigating through said at least one hollow needle as required to remove tissue, liquids and vapor in the area of the organ receiving energy delivery;

15        terminating energization of the laser energy transmitting means after the desired energy delivery is achieved;

         retracting said transmitting means from the prostatic tissue into the catheter; and

         withdrawing the catheter.

1/6



2/6

Fig. 2.

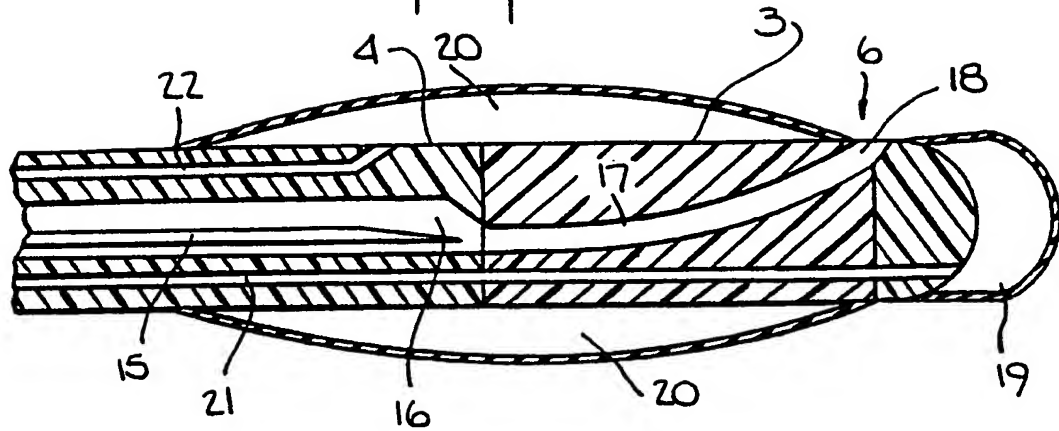
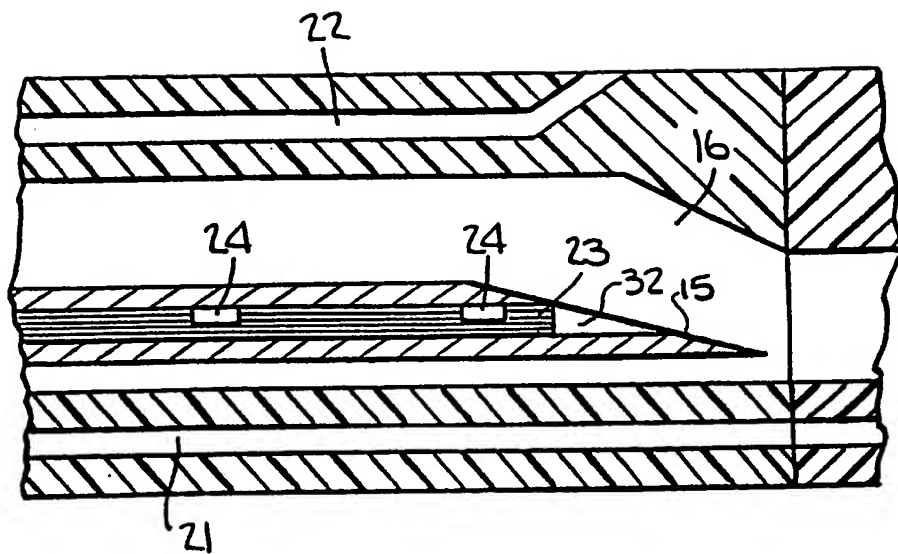
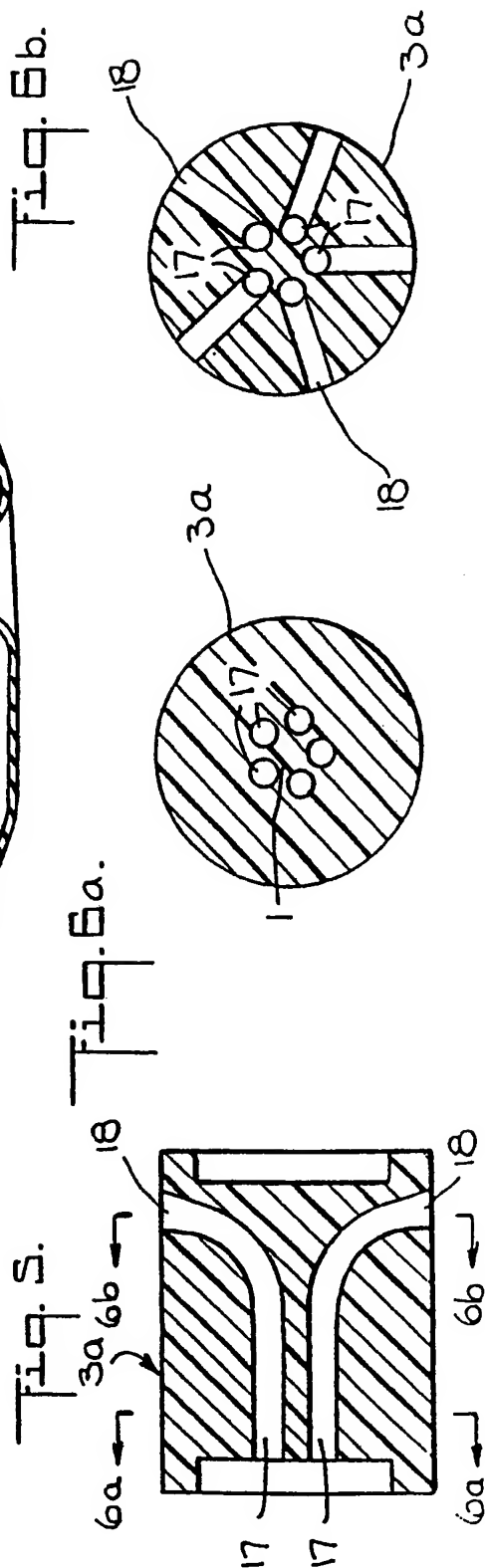
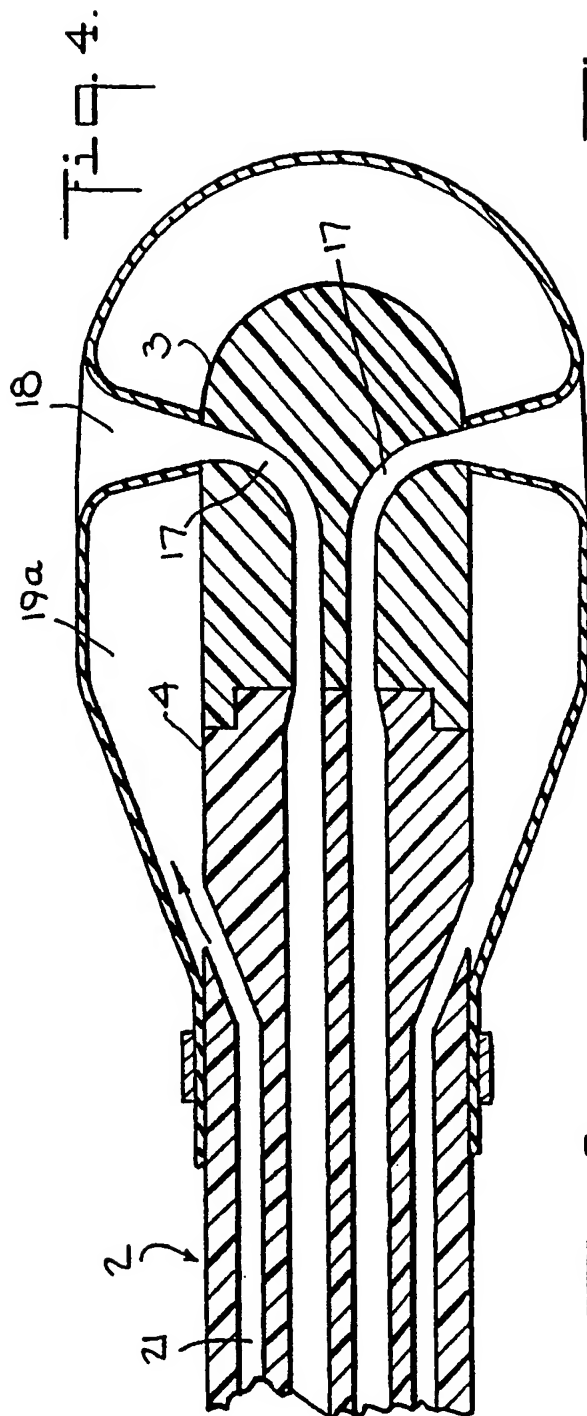
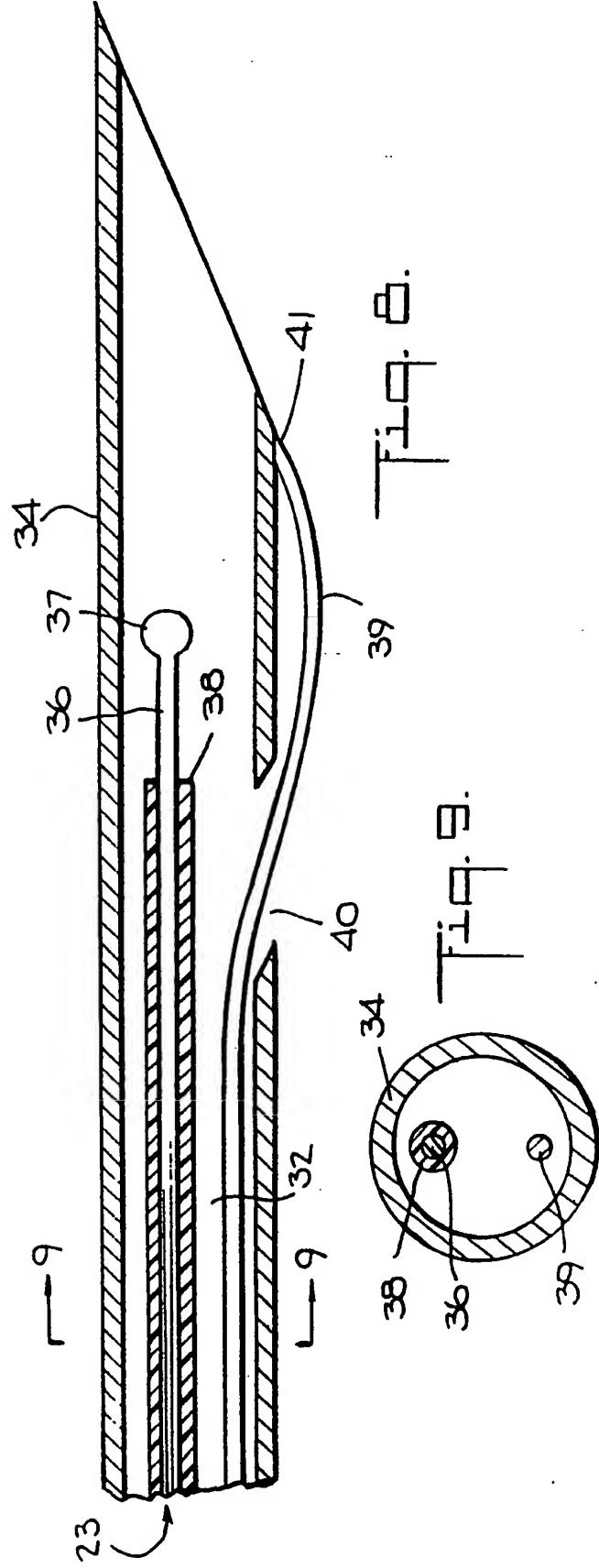
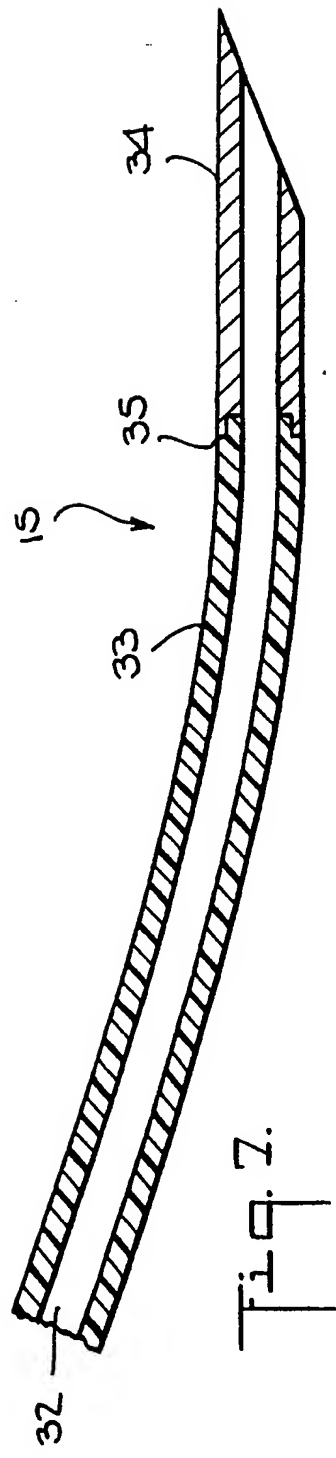


Fig. 3.



3/6





5/6

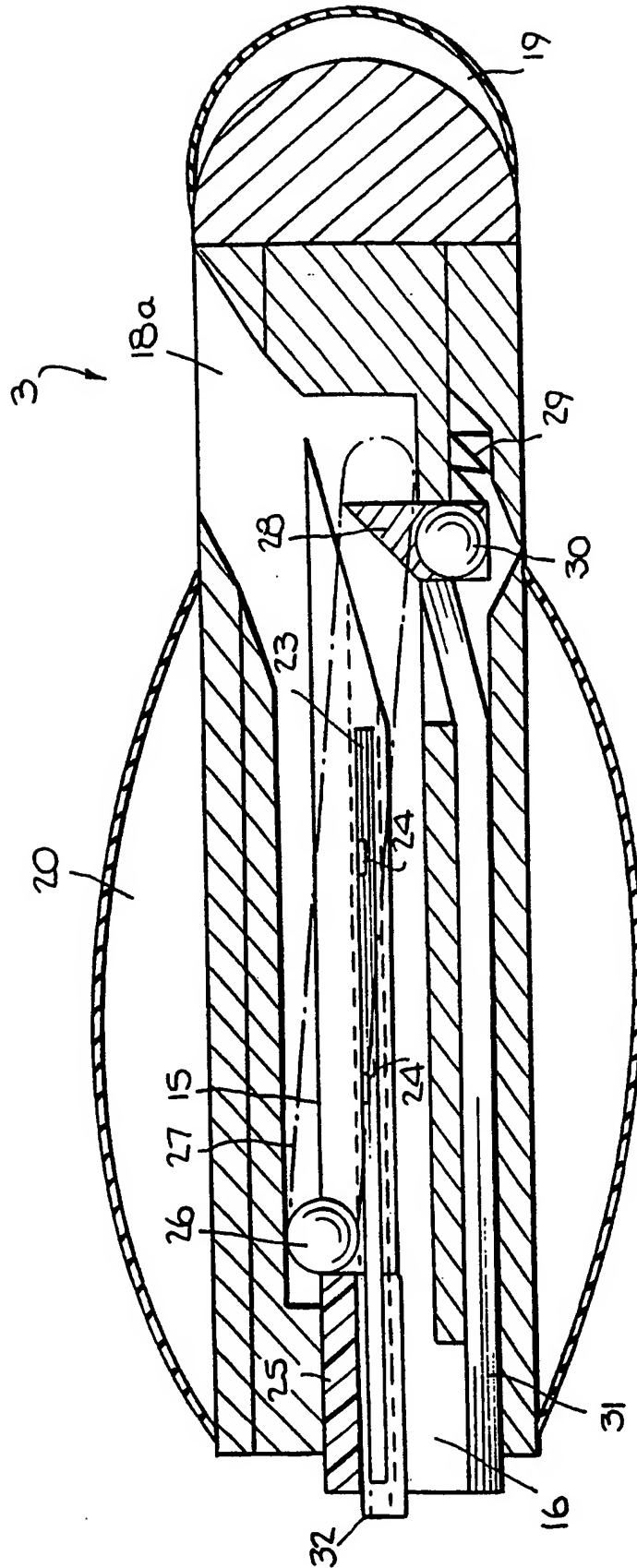


Fig. 10.

6/6

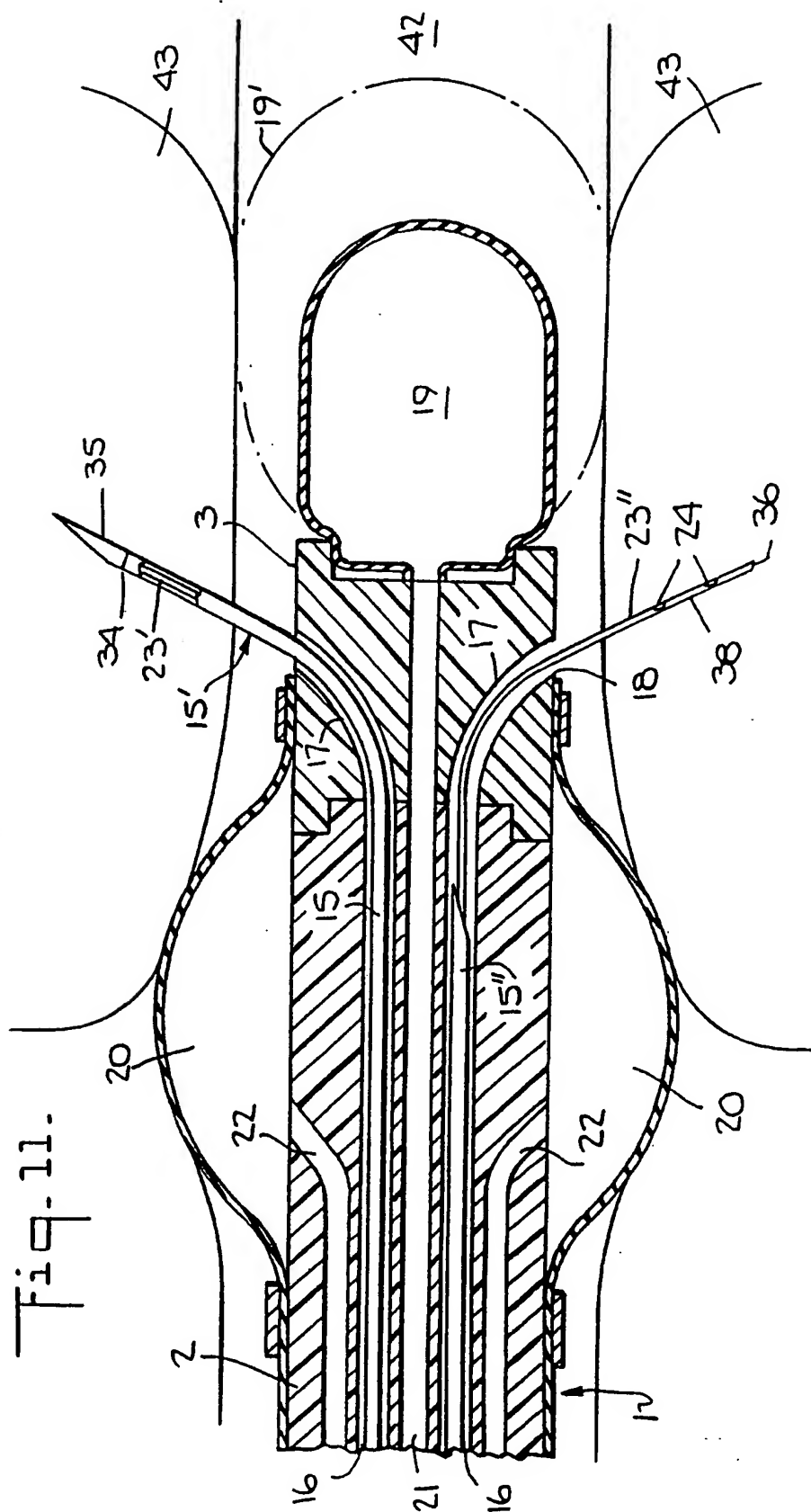



Fig. 11.

# INTERNATIONAL SEARCH REPORT

International Application No **PCT/US 91/08388**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC <b>Int.Cl.5                      A 61 B 17/36</b>		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
<b>Int.Cl.5</b>	<b>A 61 B</b>	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category <sup>o</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
1	<b>A</b> DE,A,2826383 (EICHLER et al.) 20 December 1979, see page 5, line 31 - page 6, line 1; figures 5,6 ---	1,18,25
1	<b>A</b> US,A,4950267 (ISHIHARA et al.) 21 August 1990, see column 2, lines 58,59; figure 2 (cited in the application) ---	1,18,25
1	<b>A</b> DE,A,3840749 (KOSCHER et al.) 7 June 1990, see column 3, lines 49-64; figures 1,2 ---	1,18,25
1	<b>A</b> US,A,4955882 (HAKKY) 11 September 1990, see column 4, lines 34-37 ---	25
1	<b>A</b> US,A,4760840 (FOURNIER, Jr. et al.) 2 August 1988 -----	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>o</sup> Special categories of cited documents : <sup>10</sup></p> <p><b>"A"</b> document defining the general state of the art which is not considered to be of particular relevance</p> <p><b>"E"</b> earlier document but published on or after the international filing date</p> <p><b>"L"</b> document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p><b>"O"</b> document referring to an oral disclosure, use, exhibition or other means</p> <p><b>"P"</b> document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p><b>"T"</b> later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p><b>"X"</b> document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p><b>"Y"</b> document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p><b>"A"</b> document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
<b>20-03-1991</b>		<b>28.04.92</b>
International Searching Authority		Signature of Authorized Officer
<b>EUROPEAN PATENT OFFICE</b>		 <b>Els Vonk</b>

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATION WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE <sup>1</sup>

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claim numbers 26 because they relate to subject matter not required to be searched by this Authority, namely:

PCT-Rule 39.1(iv) Method of treatment of the human body.

2. ☐ Claim numbers because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:

3. ☐ Claim numbers because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING <sup>2</sup>

This International Searching Authority found multiple inventions in this International application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this International search report covers only those claims of the International application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9108388

SA 54356

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/04/92. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 2826383	20-12-79	None	
US-A- 4950267	21-08-90	JP-A- 1139081	31-05-89
DE-A- 3840749	07-06-90	None	
US-A- 4955882	11-09-90	US-A- 5061266	29-10-91
US-A- 4760840	02-08-88	None	

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**